

**FILED**

Lisa J. Rodriguez (LR-6767)  
RODRIGUEZ & RICHARDS, LLC  
3 Kings Highway East  
Haddonfield, NJ 08003  
856-795-9002

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AT 8:30  
WILLIAM T. WALSH, CLERK

[Additional Counsel on Signature Page]

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

HIP HEALTH PLAN OF FLORIDA, INC., )  
on behalf of itself and )  
all others similarly situated, )

Plaintiff, )

v. )

SCHERING-PLOUGH CORPORATION; )  
UPSHER-SMITH LABORATORIES; and )  
AMERICAN HOME PRODUCTS )  
CORPORATION, )

Defendants. )

Case No.

01-CV-1652 (KSH)

PLAINTIFF DEMANDS A  
TRIAL BY JURY

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DISTRICT COURT

**CLASS ACTION COMPLAINT**

The above-captioned Plaintiff, on its own behalf and on behalf of all others similarly situated, alleges as follows:

**NATURE OF ACTION**

1. Plaintiff brings this civil antitrust class action on behalf of end-payors, i.e., the last persons and entities in the chain of distribution, who purchased K-Dur 20 after May 2, 1998 other than for resale. This action challenges unlawful agreements by Schering-Plough Corporation ("Schering"), Upsher-Smith Laboratories ("Upsher-Smith") and American Home

Products Corporation ("AHP") to allocate the U.S. market or submarket for 20 millicquivalent extended-release potassium chloride tablets and capsules entirely to Schering. These agreements delayed the entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20, a product used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.

2. When confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI Lederle, Incorporated ("ESI"), a division of AHP, Schering structured and entered into agreements with Upsher-Smith, AHP, and ESI that are keeping Upsher-Smith, ESI, and all other potential generic competitors out of the market. These agreements have cost third-party payors and consumers in excess of \$100 million.

#### **PARTIES**

3. Plaintiff HIP Health Plan of Florida ("HIP") is a private, not-for-profit insurance company and health maintenance organization that provides health benefits through various subsidiaries and affiliates to about 220,000 residents of Florida and other states. Through agreements with participating pharmacies, HIP pays some or all of the cost of prescription drugs dispensed to its members. HIP is a Florida corporation and maintains its principal place of business in Miami, Florida. At various times, including after May 2, 1998, HIP purchased K-Dur 20 in Florida and other states other than for resale and was injured by the illegal conduct alleged herein.

4. Defendant Schering is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-

counter healthcare and animal care products. Schering's net sales for 1999 were approximately \$9.2 billion. Throughout the period May 3, 1998 to the present, Schering manufactured and sold substantial quantities of K-Dur 20 in a continuous flow of interstate trade and commerce, and Schering's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

5. Defendant Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23<sup>rd</sup> Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development, and marketing of drugs. Upsher-Smith markets twelve brand-name products, all of which are sold in the United States. Upsher-Smith's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

6. Defendant AHP is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. AHP engages in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter medications. AHP had net sales of \$13.5 billion in 1999. AHP's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

7. ESI, a division of AHP, engages in the research, manufacture, and sale primarily of generic drugs.

#### **JURISDICTION AND VENUE**

8. Subject matter jurisdiction is proper pursuant 28 U.S.C. §§ 1331, 1332, 1337 and 1367. The amount in controversy as to the claims of Plaintiff HIP exceeds the sum or value of \$75,000, exclusive of interest and costs. The amount in controversy as to the claims of each class member also exceeds the sum or value of \$75,000, exclusive of interest and costs, as each

class member has a common and undivided interest in defendants' ill-gotten gain, for which they seek the remedy of disgorgement.

9. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 15 U.S.C. § 22.

**CLASS ALLEGATIONS**

10. Plaintiff brings this action on behalf of itself and the following Class and

Subclass:

All persons and entities in the United States who, at any time after May 2, 1998, purchased K-Dur 20 in the United States other than for re-sale (the "Nationwide End-Payor Class").

All persons and entities in the United States who, at any time after May 2, 1998, purchased K-Dur 20 in the District of Columbia, Arizona, California, Florida, Kansas, Maine, Michigan, Minnesota, Mississippi, New Mexico, New Jersey, North Carolina, North Dakota, South Dakota, Tennessee, West Virginia or Wisconsin other than for re-sale (the "17-Jurisdiction End-Payor Subclass").

Excluded from the Class and Subclass are Defendants, their subsidiaries and affiliates, and government entities. For purposes of these Class and Subclass definitions, persons and entities "purchased" K-Dur 20 if they paid some or all of the purchase price.

11. The Class and Subclass are each so numerous that joinder of all members is impracticable. While the exact size of the Class and Subclass is unknown to Plaintiff at the present time, the members of the Class and Subclass, respectively, are believed to number at least in the thousands.

12. Common questions of law and fact exist as to all members of the Class and Subclass. Among those questions are the following:

- a. whether the conspiracy alleged herein among Schering, Upsher-Smith and AHP/ESI is a *per se* or other violation of federal and state antitrust law;

- b. the date on which a generic version of K-Dur 20 would have been sold in the United States but for Defendants' unlawful conduct;
- c. whether Defendants' unlawful conduct caused Plaintiff and the other Class and Subclass members to pay more for 20 milliequivalent extended-release potassium chloride tablets and capsules than they otherwise would have paid; and
- d. the appropriate measure of the Class's and Subclass's damages.

13. These and other questions of law and fact are common to the members of the Class and Subclass and predominate over any questions affecting only individual members.

14. Plaintiff's claims are typical of the claims of other members of the Class and Subclass because Plaintiff and all Class and Subclass members sustained damages in the same way, as a result of Defendants' wrongful conduct complained of herein, and all claims for each Class and Subclass arise out of the same nucleus of operative facts and are based on the same legal theories.

15. Plaintiff will fairly and adequately protect the interest of the other Class and Subclass members. Plaintiff has retained counsel who are experienced in class action and antitrust litigation, and Plaintiff has no interest in this litigation that is adverse to or in conflict with the interest of the other members of the Class and Subclass.

16. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The damages suffered by many members of the Class and Subclass are expected to be relatively small, so that the expense and burden of prosecuting an antitrust damages case such as this one will almost certainly preclude individual litigation by

such members. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that will preclude its maintenance as a class action.

### **FEDERAL REGULATION OF PRESCRIPTION DRUGS**

17. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States.

18. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. Such new drugs are referred to as "brand name drugs" or "branded drugs." FDA approval for a branded drug is generally sought by filing a New Drug Application ("NDA") with the FDA.

19. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), to facilitate entry of generic drugs while maintaining incentives for new drug development.

20. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references.

21. When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a "Paragraph IV Certification."

22. The ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA. If, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period.

23. The Hatch-Waxman Act gives the first firm filing an ANDA for a generic version of a brand name drug with a Paragraph IV Certification a period of protection from competition from other generic versions of the drug. The FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is referred to as "the 180-day Exclusivity Period."

24. If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period.

#### **THE IMPACT OF GENERIC COMPETITION**

25. Generic entry generally leads to a significant erosion of the branded drug's market share and unit and dollar sales within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases and the branded drug's market share erodes further.

26. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that only the branded product be dispensed.

27. Certain third-party payors of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the use of generic drugs in lieu of their branded counterparts wherever possible.

**RELEVANT PRODUCT AND GEOGRAPHIC MARKET**

28. The relevant geographic market in which to evaluate the conduct of Schering, Upsher-Smith and AHP is the United States.

29. The relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including the manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

30. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain anti-hypertensive medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.

31. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.

32. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.

33. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.



### MARKET POWER

34. Schering has approximately 69% of the sales of potassium chloride supplements.

35. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.

36. At all times relevant herein, entry into the relevant market and submarket was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, has not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months.

37. At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.

38. At all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market

power in the potassium chloride supplement market.

### **DEFENDANTS' UNLAWFUL CONDUCT**

#### **Background**

39. Schering manufactures and markets two extended-release micro encapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand name drugs.

40. In 1998, sales of Schering's two K-Dur products were over \$220 million.

41. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.

42. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which claims a controlled release potassium chloride tablet. The '743 patent expires on September 5, 2006.

43. The allegedly novel aspect of the '743 patent is the composition of the coating material applied to previously known potassium chloride crystals.

44. Schering anticipated generic entry prior to expiration of its '743 patent.

45. Prior to 1997, Schering projected that the first year of low-priced generic competition would reduce branded K-Dur 20's sales by over \$30 million.

#### **Schering/Upsher-Smith Market Allocation Agreement**

46. On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV

Certification and ANDA filing.

47. Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor Con M20 infringed Schering's '743 patent. This lawsuit triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product.

48. This lawsuit was strongly contested by Upsher-Smith.

49. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day Exclusivity Period.

50. Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-Dur 20 until after the exclusivity period has expired, whether or not the other marketer has a product that infringes the Schering patent.

51. During the first half of 1997, Upsher-Smith prepared to launch commercially Klor Con M20 no later than May 1998, the month in which the 30-month stay of FDA approval was to expire.

52. On June 17, 1997, on the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the settlement, Schering agreed to make unconditional payments of \$60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products.

53. The \$60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering.

54. The licensed products were of little value to Schering. Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.

55. A court decision in the Schering patent infringement suit against Upsher-Smith would have removed barriers to generic competition, regardless of which party prevailed in the suit. If Upsher-Smith had prevailed, the FDA would have been permitted to grant final approval to Upsher-Smith's generic version of K-Dur 20, allowing Upsher-Smith to offer generic competition to Schering. After Upsher-Smith's 180-day Exclusivity Period had run, other potential generic competitors would have been eligible for final FDA approval. If Schering had prevailed, Upsher-Smith would not have been eligible for the 180-day Exclusivity Period. Since no other firm would have been eligible for the 180-day Exclusivity Period, there would have been no 180-day Exclusivity Period blocking final FDA approval of other generic competitors. Thus, the settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.

56. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.

57. Pursuant to its agreement with Schering, Upsher-Smith has not marketed Klor Con M20, nor has it attempted to develop another generic version of Schering's K-Dur 20.

58. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day

Exclusivity Period has run.

**Schering/AHP/ESI Market Allocation Agreement**

59. On December 29, 1995, ESI submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA filing.

60. ESI planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day Exclusivity Period expired.

61. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's '743 patent. Schering's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product.

62. By the end of January 1998, Schering, AHP, and ESI had reached an agreement in principle to settle their patent litigation.

63. Pursuant to their agreement in principle, Schering agreed to pay ESI up to \$30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. Schering agreed to pay ESI \$5 million up front; an additional \$10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA

under an ANDA on or before June 30, 1999; and another \$15 million for licenses of two generic products that ESI was developing. The payments for the licenses included \$5 million to be paid within ten days of execution of the agreement, plus \$10 million to be paid in annual installments over seven years.

64. Schering has made no sales to date of the two products it licensed from ESI.

65. Instead of being based on the value of the licensed products, the \$15 million license payment is based on the amount that ESI wanted in order to settle its patent litigation with Schering.

66. On June 19, 1998, Schering and ESI executed their final settlement agreement. Their patent litigation had previously been dismissed with prejudice.

67. Schering has paid ESI over \$20 million and continues to make annual payments to ESI under the terms of their agreement.

68. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expires.

#### **Other Potential Generic Competition**

69. Andrx Corporation ("Andrx") filed an ANDA for a generic version of Schering's K-Dur 20 on June 2, 1999. Schering has not sued Andrx for infringement of the '743 patent.

70. Andrx cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run.

#### **EFFECTS OF DEFENDANTS' CONDUCT**

71. The acts and practices of Defendants as herein alleged have had the purpose and effect to restrain competition unreasonably and to injure competition by preventing or

discouraging the entry of generic K-Dur 20 products into the relevant market and submarket.

72. By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher-Smith nor ESI would have agreed to delay its entry for so long.

73. By making cash payments to Upsher-Smith and ESI, Schering protected itself from competition in the relevant markets from Upsher-Smith and ESI until September 2001 and January 2004, respectively.

74. Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith is entitled to 180 days of market exclusivity before any other competitor may enter with its own generic version of K-Dur 20. By avoiding a court decision that would have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.

75. As a result of Defendants' conduct as herein alleged, third-party payors and consumers are being deprived of the benefits of competition from Upsher-Smith, ESI and other generic competitors. Without this lower-priced generic competition, third-party payors and consumers have been forced to purchase Schering's more expensive K-Dur 20 product.

**COUNT I**

**(On Behalf of the Nationwide End-Payor Class)  
Conspiracy in Violation of Section 1 of the Sherman Act**

76. Plaintiffs incorporate by reference the preceding allegations.

77. Beginning no later than June 17, 1997 and continuing to the present, Schering engaged in a continuing illegal contract, combination and conspiracy in restraint of trade with Upsher-Smith, the purpose and effect of which was to (1) allocate all sales of 20 milliequivalent extended-release potassium chloride tablets and capsules in the United States to Schering, and (2) prevent the sale of generic 20 milliequivalent extended-release potassium chloride tablets and capsules in the United States, thereby protecting K-Dur 20 from any generic competition. Beginning no later than January 1998 and continuing to the present, AHP and ESI joined the continuing illegal contract, combination and conspiracy in restraint of trade, which was expanded for the purpose, and with the effect, of also preventing future competition between Schering and AHP/ESI, thereby further protecting K-Dur 20 from any generic competition.

78. In furtherance of this contract, combination and conspiracy, Defendants did those things which they conspired and combined to do, including:

- a. Schering and Upsher-Smith entered into the June 17, 1997 settlement agreement;
- b. Schering paid \$60 million to Upsher-Smith under the settlement agreement;
- c. Upsher-Smith has refrained from entering the U.S. market for 20 milliequivalent extended-release potassium chloride tablets and capsules;
- d. Schering, AHP and ESI agreed to settle their patent litigation in January



1998;

- e. Schering has paid over \$20 million to ESI and continues to make annual payments to ESI under the settlement agreement; and
- f. AHP and ESI have refrained from entering the U.S. market for 20 milliequivalent extended-release potassium chloride tablets and capsules.

79. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade in *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. In the alternative, Defendants' conspiracy was an unreasonable restraint of trade and violates § 1 of the Sherman Act under a rule of reason analysis.

80. Plaintiffs and the other members of the Nationwide End-Payor Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Their injury consists of paying higher prices for 20 milliequivalent extended-release potassium chloride tablets and capsules than they would have paid in the absence of Defendants' unlawful conduct.

## COUNT II

### **(On Behalf of the 17-Jurisdiction End-Payor Subclass) Conspiracy in Violation of State Law**

81. Plaintiffs incorporate by reference the preceding allegations.

82. Beginning no later than June 17, 1997 and continuing to the present, Schering engaged in a continuing illegal contract, combination and conspiracy in restraint of trade with Upsher-Smith, the purpose and effect of which was to (1) allocate all sales of 20 milliequivalent extended-release potassium chloride tablets and capsules in the United States to Schering, and (2) prevent the sale of generic 20 milliequivalent extended-release potassium chloride tablets and

capsules in the United States, thereby protecting K-Dur 20 from any generic competition.

Beginning no later than January 1998 and continuing to the present, AHP and ESI joined the continuing illegal contract, combination and conspiracy in restraint of trade, which was expanded for the purpose, and with the effect, of also preventing future competition between Schering and AHP/ESI, thereby further protecting K-Dur 20 from any generic competition.

83. In furtherance of this contract, combination and conspiracy, Defendants did those things which they conspired and combined to do, including:

- a. Schering and Upsher-Smith entered into the June 17, 1997 settlement agreement;
- b. Schering paid \$60 million to Upsher-Smith under the settlement agreement;
- c. Upsher-Smith has refrained from entering the U.S. market for 20 milliequivalent extended-release potassium chloride tablets and capsules;
- d. Schering, AHP and ESI agreed to settle their patent litigation in January 1998;
- e. Schering has paid over \$20 million to ESI and continues to make annual payments to ESI under the settlement agreement; and
- f. AHP and ESI have refrained from entering the U.S. market for 20 millicquivalent extended-release potassium chloride tablets and capsules.

84. By entering into this unlawful conspiracy, Defendants have unlawfully conspired in restraint of trade in *per se* violation of the state statutes identified below. In the alternative, Defendants' conspiracy was an unreasonable restraint of trade and violates the state statutes

identified below under a rule of reason analysis.

85. Defendants' conspiracy violates Arizona Revised Stat. §§ 44-1401 *et seq.*, with respect to purchases of K-Dur 20 in Arizona by members of the 17-Jurisdiction End-Payor Subclass.

86. Defendants' conspiracy violates Cal. Bus. & Prof. Code §§ 17200 *et seq.*, with respect to purchases of K-Dur 20 in California by members of the 17-Jurisdiction End-Payor Subclass.

87. Defendants' conspiracy violates D.C. Code Ann. §§ 28-4502 *et seq.*, with respect to purchases of K-Dur 20 in the District of Columbia by members of the 17-Jurisdiction End-Payor Subclass.

88. Defendants' conspiracy violates Fla. Stat. §§501.201 *et seq.*, with respect to purchases of K-Dur 20 in Florida by members of the 17-Jurisdiction End-Payor Subclass.

89. Defendants' conspiracy violates Kan. Stat. Ann. §§50-101 *et seq.*, with respect to purchases of K-Dur 20 in Kansas by members of the 17-Jurisdiction End-Payor Subclass.

90. Defendants' conspiracy violates Me. Rev. Stat. Ann. 10, §1101 *et seq.*, with respect to purchases of K-Dur 20 in Maine by members of the 17-Jurisdiction End-Payor Subclass.

91. Defendants' conspiracy violates Mich. Comp. Laws Ann. §§ 445.771 *et seq.*, with respect to purchases of K-Dur 20 in Michigan by members of the 17-Jurisdiction End-Payor Subclass.

92. Defendants' conspiracy violates Minn. Stat. §§325D.49 *et seq.* with respect to purchases of K-Dur 20 in Minnesota by members of the 17-Jurisdiction End-Payor Subclass.

93. Defendants' conspiracy violates Miss. Code Ann. §§75-21-1 *et seq.*, with respect to purchases of K-Dur 20 in Mississippi by members of the 17-Jurisdiction End-Payor Subclass.

94. Defendants' conspiracy violates N.J. Stat. Ann. §§56:9-1 *et seq.*, with respect to purchases of K-Dur 20 in New Jersey by members of the 17-Jurisdiction End-Payor Subclass.

95. Defendants' conspiracy violates N.M. Stat. Ann. §§57-1-1 *et seq.*, with respect to purchases of K-Dur 20 in New Mexico by members of the 17-Jurisdiction End-Payor Subclass.

96. Defendants' conspiracy violates N.C. Gen. Stat. §§75-1, *et seq.*, with respect to purchases of K-Dur 20 in North Carolina by members of the 17-Jurisdiction End-Payor Subclass.

97. Defendants' conspiracy violates N.D. Cent. Code §51-08.1-01 *et seq.*, with respect to purchases of K-Dur 20 in North Dakota by members of the 17-Jurisdiction End-Payor Subclass.

98. Defendants' conspiracy violates S.D. Codified Laws Ann. §37-1 *et seq.*, with respect to purchases of K-Dur 20 in South Dakota by members of the 17-Jurisdiction End-Payor Subclass.

99. Defendants' conspiracy violates Tenn. Code Ann. §§47-25-101 *et seq.*, with respect to purchases of K-Dur 20 in Tennessee by members of the 17-Jurisdiction End-Payor Subclass.

100. Defendants' conspiracy violates W.Va. Code §§47-18-1 *et seq.*, with respect to purchases of K-Dur 20 in West Virginia by members of the 17-Jurisdiction End-Payor Subclass.

101. Defendants' conspiracy violates Wis. Stat. §133.01 *et seq.*, with respect to purchases of K-Dur 20 in Wisconsin by members of the 17-Jurisdiction End-Payor Subclass.

102. Plaintiffs and the other members of the 17-State End-Payor Subclass have been

injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Their injury consists of paying higher prices for 20 milliequivalent extended-release potassium chloride tablets and capsules than they would have paid in the absence of the Defendants' unlawful conduct

### **COUNT III**

#### **(On Behalf of the Nationwide End-Payor Class) Unjust Enrichment Under State Law**

103. Plaintiffs incorporate by reference the preceding allegations.

104. Defendants have benefitted from their unlawful acts alleged herein in several ways, including: (a) Schering received profits from sales of K-Dur 20 after May 2, 1998 that it would not otherwise have received; (b) Upsher-Smith received the \$60 million payment from Schering; and (c) ESI received over \$20 million in payments from Schering. These profits of Schering and payments received by Upsher-Smith and ESI derived at least in part from Plaintiffs' and the Nationwide End-Payor Class' overpayments for 20 milliequivalent extended-release potassium chloride tablets and capsules. It would be inequitable for Defendants to be permitted to retain any of their ill-gotten gain.

105. Plaintiffs and the Nationwide End-Payor Class are entitled to the establishment of a constructive trust consisting of all their overpayments from which Plaintiffs and the other class members may make claims on a pro rata basis for restitution.

**COUNT IV**

**(On Behalf of the Nationwide End-Payor Class)  
Injunctive Relief Under Federal Law**

106. Plaintiffs incorporate by reference the preceding allegations.

107. The unlawful conspiracy alleged herein, the actions taken pursuant thereto, and the effects thereof, are continuing and will continue unless the following preliminary and permanent injunctive relief is granted under Section 16 of the Clayton Act:

- a. Defendants shall immediately terminate the agreements by which they settled their patent lawsuits;
- b. Schering shall immediately license for no compensation its '743 patent to Upsher-Smith and to ESI so as to allow the latter two companies to make, produce, and market commercially generic versions of Schering's K-Dur 20 and K-Dur 10. Said license must eliminate any and all legal claims that Schering would have for patent infringement by Upsher-Smith and ESI for selling the generic potassium chloride products for which each has already filed an ANDA with the FDA.
- c. Upsher-Smith shall immediately relinquish its right to a 180-day Exclusivity Period for Klor Con M20.
- d. Each Defendant shall take such other measures as are appropriate to correct, remedy and prevent the recurrence of the anticompetitive practices alleged herein.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against Defendants for the following relief:

- A. A declaration that Defendants have committed the violations alleged herein;
- B. A judgment for the damages sustained by Plaintiffs and the Class and Subclass defined herein, and for any additional damages, penalties and other monetary relief provided by applicable law including treble damages;
- C. Disgorgement of Defendants' unjust enrichment;
- D. A preliminary and permanent injunction as requested in Count IV herein;
- E. The costs of this suit, including a reasonable attorneys' fee; and
- F. Such other and further relief as the Court deems just and proper.

**JURY DEMANDED**

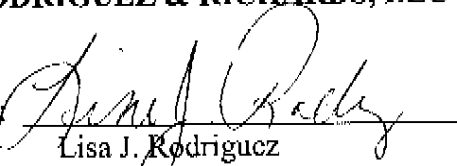
Plaintiffs demand a trial by jury of all issues so triable.

Dated: April 4, 2001

Respectfully submitted,

**RODRIGUEZ & RICHARDS, LLC**

By



Lisa J. Rodriguez  
3 Kings Highway East  
Haddonfield, NJ 08033  
(856) 795-9002

**RODRIGUEZ & RICHARDS, LLC**

Ira Neil Richards  
The Penthouse  
226 W. Rittenhouse Square  
Philadelphia, PA 19103  
(215) 731-9004

**COHEN, MILSTEIN, HAUSFELD  
& TOLL, P.L.L.C.**

Michael D. Hausfeld  
Daniel A. Small  
1100 New York Avenue, N.W.  
West Tower, Suite 500  
Washington, D.C. 20005  
(202) 408-4600

**COHEN, MILSTEIN, HAUSFELD  
& TOLL, P.L.L.C.**

Linda P. Nussbaum  
825 Third Avenue, 30<sup>th</sup> Floor  
New York, NY 10022  
(212) 838-7797



HANZMAN CRIDEN CHAYKIN  
& ROLNICK, P.A.

Michael Criden  
Commercebank Building  
220 Alhambra Circle  
Suite 400  
Coral Gables, Florida 33134  
(305) 357-9018

Attorneys for Plaintiffs

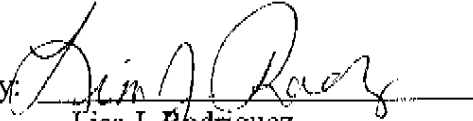
**CERTIFICATION**

I hereby certify that the matter in controversy is not the subject of any other court,  
arbitration or administrative proceeding.

Dated: April 4, 2001

Respectfully submitted,

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Haddonfield, NJ 08033  
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Attorneys for Plaintiffs